K090401

510(k) Summary

ORTHOSS®

JAN - 8 2010

1. SPONSOR

Ed. Geistlich Soehne Ag für Chemische Industrie
Geistlich Pharma Ag
Bahnhofstrasse 40
CH-6110 Wolhusen
SWITZERLAND

Contact Person: Peter S. Reichertz, (202) 772-5333
Date Prepared: January 8, 2010

2. DEVICE NAME

Proprietary Name	ORTHOSS® Resorbable Bone Void Filler
Common/Usual Name:	Resorbable Bone Void Filler
Classification Name:	Resorbable calcium salt bone void filler (MQV) 21 CFR § 888.3045

3. PREDICATE DEVICES

ORTHOSS® (K01-4289)
BIO-OSS® (K03-3815)

4. INTENDED USE

ORTHOSS® Resorbable Bone Void Filler is indicated for bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). ORTHOSS® is indicated only for use in bone voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
ORTHOSS® Resorbable Bone Void Filler is intended to be used in the spine only in posterolateral fusion.

5. DEVICE DESCRIPTION

ORTHOSS® is a natural non-antigenic, porous bone mineral. It is produced by removal of all organic components from bovine bone. Due to its natural structure, it is physically and chemically comparable to the mineralized matrix of human bone.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

ORTHOSS® is similar to the previously cleared ORTHOSS® product sourced from U.S. bone. The only change is the source of the bovine bone used to make the product from the U.S. sourced bovine bone, to Australia sourced bovine bone. Australia has been found to have a level I geographical BSE – Risk by the European Union, which means it is highly unlikely that there is the presence of one or more cattle clinically or preclinically infected with the BSE agent in Australia. Australia is also **not** on the U.S. Department of Agriculture's list of countries where BSE is known to exist. See 9 C.F.R. § 94.18. Therefore, the use of Australia source bone will not negatively impact the safety of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ed. Geistlich Soehne Ag für Chemische Industrie
% Sheppard Mullin Richter & Hampton LLP
Mr. Peter S. Reichertz
1300 I Street, N.W., 11th Floor, East
Washington, District of Columbia 20005

JAN - 8 2010

Re: K090401
Trade/Device Name: ORTHOSS® Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: December 24, 2009
Received: December 30, 2009

Dear Mr. Reichertz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K090401_____

Device Name: ORTHOSS® Resorbable Bone Void Filler.

Indications for Use: ORTHOSS® Resorbable Bone Void Filler is indicated for bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis).
ORTHOSS® is indicated only for use in bone voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
ORTHOSS® Resorbable Bone Void Filler is intended to be used in the spine only for posterolateral fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use ___ (21 CFR 801 Subpart C)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090401